



Billing Code: 4150-36-P

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Meeting of the Secretary's Advisory Committee on Human Research Protections**

**AGENCY:** Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary for Health.

**ACTION:** Notice.

**SUMMARY:** Pursuant to Section 10(a) of the Federal Advisory Committee Act, notice is hereby given that the Secretary's Advisory Committee on Human Research Protections (SACHRP) will hold a meeting that will be open to the public. Information about SACHRP, the full meeting agenda, and instructions for linking to public access will be posted on the SACHRP website at <http://www.dhhs.gov/ohrp/sachrp-committee/meetings/index.html>.

**DATES:** The meeting will be held on Wednesday, July 22, 2020, from 11:00 a.m. until 4:30 p.m., and Thursday, July 23, 2020, from 11:00 a.m. until 4:30 p.m. (times are tentative and subject to change). The confirmed times and agenda will be posted at on the SACHRP web site when this information becomes available.

**ADDRESSES:** This meeting will be held via webcast. Members of the public may also attend the meeting via webcast. Instructions for attending via webcast will be posted one week prior to the meeting at <https://www.hhs.gov/ohrp/sachrp-committee/meetings/index.html>.

**FOR FUTHER INFORMATION CONTACT:** Julia Gorey, J.D., Executive Director, SACHRP; U.S. Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, Maryland 20852; telephone: 240-453-8141; fax: 240-453-6909; e-mail address [SACHRP@hhs.gov](mailto:SACHRP@hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the authority of 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended, SACHRP was established to provide expert advice and recommendations to the Secretary of Health and Human Services, through the Assistant Secretary for Health, on issues and topics pertaining to or associated with the protection of human research subjects.

The Subpart A Subcommittee (SAS) was established by SACHRP in October 2006 and is charged with developing recommendations for consideration by SACHRP regarding the application of subpart A of 45 CFR part 46 in the current research environment.

The Subcommittee on Harmonization (SOH) was established by SACHRP at its July 2009 meeting and charged with identifying and prioritizing areas in which regulations and/or guidelines for human subjects research adopted by various agencies or offices within HHS would benefit from harmonization, consistency, clarity, simplification and/or coordination.

The SACHRP meeting will open to the public at 11:00 a.m., on Wednesday, July 22, 2020, followed by opening remarks from Dr. Jerry Menikoff, Director of OHRP and Dr. Stephen Rosenfeld, SACHRP Chair. The meeting will begin with presentation of

recommendations on the NIH Draft Data Management and Sharing Policy. This will be followed by a review of the Deceased Organ Intervention Research recommendations, and edits discussed at the March SACHRP meeting. The remainder of the meeting will be devoted to a new topic, the interpretation of Public Health Surveillance, 45 CFR 46.102(l)(2) and 46.102(k). The second day, July 23<sup>rd</sup>, will again host discussion of Public Health Surveillance, 45 CFR 46.102(l)(2) and 46.102(k), as well as consideration of a second new topic, Risks to Non-subjects in Human Subjects Research. For the full and updated meeting agenda, see <http://www.dhhs.gov/ohrp/sachrp-committee/meetings/index.html>.

The public will have an opportunity to comment to the SACHRP during the meeting's public comment session or by submitting written public comment. Persons who wish to provide public comment should review instructions at <https://www.hhs.gov/ohrp/sachrp-committee/meetings/index.html> and respond by midnight Wednesday, July 17, 2020, ET. Individuals submitting written statements as public comment should submit their comments to SACHRP at [SACHRP@hhs.gov](mailto:SACHRP@hhs.gov). Verbal comments will be limited to three minutes each.

Time will be allotted for public comment on both days. Note that public comment must be relevant to topics currently being addressed by the SACHRP.

**Dated:** June 30, 2020.

Julia G. Gorey,

Executive Director,

Secretary's Advisory Committee on Human Research Protections.

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